DECLARATION OF CHARLES A. MESKO UNDER 37 C.F.R. § 1.132

1. I, Charles A. Mesko, hereby state and declare the following:

2. I am the named inventor on the present application, U.S. Serial No. 10/790,417 ("the '417 Application"). For the extent of most of my adult life, I have devoted my work to the study of herbs, dietary supplements, natural medicine, and homeopathy. I was awarded a Doctorate in Naturopathy (2005) from Central States College of Health Sciences, Columbus Ohio.

3. I taught natural health and traditional homeopathy at Central States College of Health Sciences (2005-2006) and conducted clinical research in the use of homeopathic remedies and medicine for pain relief (at Central States College of Health Sciences, Columbus, Ohio from 2005-2006).

4. I am the founder of and product formulator for Fountain of Youth Technologies, Inc., a company offering homeopathic medicines and herbal supplements for sale to naturopathic doctors, health food stores, consumers, and for export. Fountain of Youth Technologies, Inc. is assigned Labeler Code # 66978 by the Food and Drug Administration (FDA) to register Fountain of Youth Technologies, Inc.'s homeopathic products.

5. I currently serve on the board of directors of the non-profit Mid-American Health Organization. The members of this organization are health food store owners, naturopathic doctors and manufacturers dedicated to promoting natural

products and homeopathic medicines in Illinois, Indiana, Iowa, Kentucky, Michigan, Minnesota, Missouri, Ohio, West Virginia, and Wisconsin.

6. I have been a featured guest speaker at seminars on homeopathic medicine and natural herbal supplements. I have been featured on local and nationally syndicated radio shows explaining homeopathy. I was a featured guest interviewed by Robert Scott Bell (Diplomate of the American Academy of Clinical Homeopathy) to discuss homeopathic preparations and medicines on the nationally syndicated Robert Scott Bell Show broadcast from The Natural Products Association Tradeshow held June 16, 17 and 18, 2006 in Las Vegas, Nevada. The Natural Products Association, founded in 1936, is the nation's oldest and largest non-profit organization dedicated to promoting natural products and homeopathic preparations. On September 20 and 21, 2008 I was again a featured guest on the nationally syndicated Robert Scott Bell Show broadcast live from the MAHO (Mid-American Health Organization) Natural Health Education and Tradeshow held September 19, 20, and 21, 2008 in St. Charles, Illinois. I was introduced by Robert Scott Bell as an expert on homeopathic medicine and as the inventor of new and remarkably effective homeopathic medicines using liposome based creams and gels to transport homeopathic ingredients through the skin into the bloodstream offering superior bioavailability. Robert Scott Bell interviewed me to explain this new and highly effective form of homeopathic medicine to his listeners and to answer questions from listeners on homeopathic medicine.

7. Currently, and over the past decade, I have been conducting research for improving the absorption, bioavailability and delivery of traditional homeopathic medicine as prepared in accordance with the exact specifications of The Homeopathic Pharmacopoeia of the United States.

8. I have reviewed the references cited against the claims of the '417 Application, including Chiou et al., "Vasorelaxing Effect of Coumarins from *Cnidium monnieri* on Rabbit Corpus Cavernosum," Planta Med., 67, (2001), pp. 282-284 ("Chiou") and Chen et al., "Therapeutic patent for topical and transdermal drug delivery systems," Exp. Opin. Ther. Patents, (2000), 10(7), pp. 1035-1043 ("Chen"). In my opinion, as one skilled in the art, a composition including a coumarin and a vesicle for transdermal delivery would not be obvious in view of Chiou and Chen. In particular, the knowledge of those of ordinary skill in the art regarding coumarins (such as those described in Chiou) teaches away from transdermal delivery via vesicles (such as those described in Chen).

9. Chiou is a study of the effects of four known coumarins (osthole, imperatorin, xanthotoxin, and isopimpinellin) on penile erectile tissue. The effects of these coumarins were tested by excising the corpus cavernosum tissue from rabbits, and subjecting the tissue to cumulative additions of the four coumarins, as described at p. 283 of Chiou. However, Chiou does not include any discussion as to how such

coumarins would be delivered to a living subject. However, the study of Chiou is related to drugs that are used for the treatment of erectile dysfunction. Existing drugs for erectile dysfunction are generally ingested by the patient, rather than being delivered by other means (e.g., transdermally, parenterally, etc.). Thus, it is my view, as a person of ordinary skill in the art, that the study of Chiou would be used in preparing drugs or compositions including coumarins that would be delivered via ingestion by a subject.

10. And there are reasons why compositions including coumarins would be delivered via ingestion, and why those of ordinary skill in the art would not transdermally deliver compositions including coumarins. Coumarins include chemical compounds that are toxins, and are moderately toxic to the liver and kidneys. In fact, coumarins have been banned as a food additive in numerous countries since the mid-20th century because of the clinical demonstration of coumarins being moderately toxic to both the liver and kidneys. European health agencies have warned against consuming high amounts of cassia bark, one of the four species of common cinnamon, because of its coumarin content. And, coumarin was banned as a food additive in the United States in 1978, and is currently listed by the United States Food and Drug Administration among "Substances Generally Prohibited from Direct Addition or Use as Human Food."

11. However, in smaller amounts, humans can metabolize coumarins, and certain studies have established tolerable daily intakes of coumarins when

ingested, because they are subjected to processing by the human system, including the liver. As is known to those of ordinary skill in the art, the liver plays a major role in metabolism, and has a number of functions in the body, including detoxification of substances that are ingested (known as the "first-pass effect"). The first-pass effect is part of drug metabolism whereby the concentration of a drug is reduced before it reaches the circulatory system. In particular, as is known to those of ordinary skill in the art, after a drug is swallowed, it is absorbed by the digestive system and is carried into the liver before it reaches the rest of the body. The liver metabolizes the drug, sometimes such that only a small amount of active drug emerges from the liver to the circulatory system. This first-pass effect reduces the toxicity of coumarins.

12. However, transdermal delivery (e.g., through the use of liposomes), avoids the first-pass effect because it allows the composition to be absorbed directly into the bloodstream. In fact, Chen (at p.1035) specifically states that "[t]he use of a transdermal drug delivery system can avoid first pass hepatic or intestinal metabolism . . ." As a result, while one of ordinary skill in the art would deliver a composition including coumarins via ingestion, they would not deliver such a composition transdermally via a vesicle [because they would consider that bypassing the liver (by using a liposome) would allow the coumarins to retain toxicity]. Thus, a person of ordinary skill in the art would not think to deliver a coumarin in a transdermal manner, and thus would not prepare or provide a transdermal composition including a coumarin (as claimed in the

'417 Application). Thus, the present invention is a complete change in direction from that known by those of ordinary skill in the art, and taught in the cited art.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Further Declarant sayeth naught.

October 29, 2008
Date

Charles A. Mesko